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DE-A- 2 708 607
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JOURNAL OF PHYSICS E. SCIENTIFIC INSTRUMENTS, vol. 10, no. 10, October 1983, pages 987-994, Dorking, GB; **J.M.L. ENGEL et al.**: "Medical applications of silicon sensors"

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Description

The present invention relates to a catheter including a sensor which is inserted into a living body through, for example, a blood vessel, to measure directly within the living body biological data such as blood pressure, the pH of the blood and the degree of saturation of oxygen in the blood.

Conventionally such a catheter comprises a sensor assembly including a base with at least one sensor element supported on it for detecting biological data, and a catheter body portion supporting the sensor assembly at its distal end or at an intermediate portion and including lead wires for transmitting data between the sensor element and an external measuring device. In such a conventional catheter the sensing assembly consisting of the base, the sensor element and the lead wires is mounted inside the bore of a thick-walled armoring tube forming the catheter. Since this tube provides the chief structural component of the catheter its wall thickness must be substantial and this, surrounding the outside of the sensor assembly means that the catheter has a substantial diameter. Desirably the diameter of the catheter is made as small as possible to enable it to be located in small diameter blood vessels and to reduce its effect on them.

Conventional catheters including sensor assemblies and armoring tubes are disclosed in DE-A-2708607 and in an article entitled "Medical applications of silicon sensors" by J.M.L. Engles and M.H. Kuypers, published in Journal of Physics E. Scient.Inst. Vol 10(1983). In the first of these the armoring tube is cut away from part of the tip at the location of the sensor assembly and then the sensor assembly is encapsulated in a resin material moulded into the cut away portion of the tip.

According to this invention the catheter is formed of a biocompatible resin material in which the sensor assembly and the lead wires are embedded.

With a sensor in accordance with this invention, since the sensor assembly is rigidly buried in a resin material which forms the catheter, the resin material has no bore such as that of the conventional armoring tube and the whole cross-sectional area of this resin material and hence of the catheter can be used as a space available for mounting the sensor assembly. It is therefore possible for the catheter according to the present invention to provide a larger mounting space than that of the conventional catheter, with the same outer diameter. Accordingly, it is possible readily to cope with the need to provide a catheter having a composite sensor means or a multiplicity of functions and also possible to reduce the outer diameter of the catheter as compared with the conventional catheter

having a sensor element of the same size.

Particular examples of catheters in accordance with this invention will now be described and contrasted with the prior art with reference to the accompanying drawings; in which:-

Figures 1(a) and 1(b) are longitudinal vertical and horizontal sections, respectively, of one example of the catheter according to the present invention;

Figure 1(c) is a cross-section taken substantially along the line C - C shown in Figure 1(a);

Figures 2(a), 2(b) and 2(c) show in combination a second example of the catheter according to the present invention, which are similar to figure 1(a), 1(b) and 1(c), respectively;

Figure 3(a) is a longitudinal vertical section of one example of conventional catheter; and,

Figure 3(b) is a cross-section view taken substantially along the line B - B shown in figure 3(a).

A typical conventional catheter which is inserted into, for example, a blood vessel to measure biological data such as blood pressure, the pH of the blood and the saturation degree of oxygen in the blood has an arrangement such as shown in Figures 3(a) and 3(b). More specifically, a sensor element 1 for detecting biological data such as blood pressure, a base 3 for supporting the sensor element 1 and lead wires 5 for electrically connecting the sensor element 1 to an external measuring device (not shown) are assembled together in advance, inserted into the bore in a sheathing tube 7 which is fabricated in advance, and positioned in such a manner that the sensitive surface of the sensor element 1 faces a measuring window 9 provided in the tube 7. In this state, the gap between the tube 7 and the assembly constituted by the sensor element 1, the base 3 and the lead wires 5 is filled with a sealing resin 11, as also is the distal end portion of the tube 7, the assembly thereby being secured in position within the tube 7 and a catheter thus being completed. In some cases, a sensor protecting film 13 is provided over the measuring window 9 so as to protect the sensitive surface of the sensor element 1.

The conventional catheter suffers, however, from the following problems. Namely, since the assembly which is constituted by the sensor element 1, the base 3 and the lead wires 5 is inserted into the bore in the sheathing tube 7, the space which could be effectively utilized for mounting the assembly is narrowed by the wall thickness of the tube 7. More specifically, the effective cross-sectional area which can be used to mount the assembly is what remains after subtraction of the wall thickness of the tube 7 from the total cross-sectional area determined by the outermost diameter of the sensor, i.e. the tube, which means that the cross-sectional area of the tube 7 cannot be utilized effectively. In the above-described structure

of the conventional catheter, the wall thickness of the tube 7 cannot be reduced to any great extent since the greater part of the structural strength required of a catheter depends on the strength of the tube 7, and it is therefore impossible to utilize the relatively thick wall portion of the tube 7 for mounting the sensor assembly. Accordingly, it has been difficult to cope with the need to reduce the diameter of the sensor, to assemble together a plurality of kinds of sensor elements in order to form a composite sensor means without substantially increasing the outer diameter of the catheter, or to incorporate a tube for injection of a medical fluid or for collection of blood in the above-described arrangement so as to provide a multifunctional catheter without substantially increasing the outer diameter of the sensor.

Preferred embodiments of the present invention will be described hereinunder the detail.

Figures 1(a), 1(b) and 1(c) show in combination one embodiment of the present invention which is formed as a catheter adapted to be inserted into a blood vessel for direct measurement of blood pressure.

Referring to Fig. 1, a semiconductor diaphragm type pressure sensor element 21 is rigidly welded to the surface of a long plate-shaped base 23 using a gold-silicon alloy, the base 23 being made from a sintered material containing aluminum oxide as its principal component. The reason why such a sintered material is employed to form the base 23 is that this kind of sintered material has heretofore been used to form packages for semiconductor IC's and it is therefore possible to use existing IC packaging techniques to package the sensor element 21, and also that said sintered material is stable in vivo. The base 23 has an air vent 27 which communicates with the space defined at the rear side of the diaphragm 25 of the sensor element 21. The base 23 also has wiring patterns 29 printed on its surface for the purpose of electrically connecting therethrough the sensor element 21 to an external measuring device (not shown). More specifically, the sensor element 21 and the wiring patterns 29 formed on the base 23 are connected by means of bonding wires 31, whereas the wiring patterns 29 and lead wires 33, e.g., enamelled wires, which are connected to the external measuring device are connected by means of soldering. It is preferable to adopt wedge bonding in order to lower the loop height at the wire connection and to thereby enable a further reduction in the outer diameter of the catheter type sensor in its final assembled state.

The sensor element 21 may electrically detect the degree to which the diaphragm 25 is deflected in accordance with the level of blood pressure, and it is necessary to maintain the reverse side of the

diaphragm 25 under atmospheric pressure in order to measure blood pressure with the atmospheric pressure used as a reference. For this purpose, one end of an air vent tube 35 is connected to the air vent 27 in the base 23 which communicates with the space defined at the rear side of the diaphragm 25, and the other end of the tube 35 opens into the atmosphere. The sensor element 21, the bonding wires 31 and the base 23 are coated with a protection resin material 37 for the purposes of maintaining the airtight sealing connection between the sensor element 21, the air vent 27 in the base 23 and the air vent tube 35, of supporting and reinforcing the bonding wires 31 and of forming round portions at the corners of sensor element 21.

Thus, the sensor element 21, the base 23 and the lead wires 33 are connected, together with the air vent tube 35, and are coated with the protection resin material 37. This assembly is then shaped in the form of the distal end portion of a catheter type sensor by an integral molding technique using a molding resin material 39 in such a manner that the surface of the diaphragm 25 of the sensor element 21 is exposed. It is preferable to employ urethane or silicone resin material which has excellent compatibility with a living body as the molding resin material 39. In this molding process, a lumen 43 having an opening 41 may be formed in the molded article for the purpose of collection of blood or injection of a medical fluid. It should be noted that the whole surface of the catheter type sensor including the surface of the sensor element 21 is preferably coated with a urethane resin material 45 for the purpose of further improving its compatibility with living bodies and of protecting the whole of the sensor.

The catheter type sensor thus arranged is inserted into a blood vessel to output an electric signal representing the blood pressure applied to the diaphragm 25 so as to measure the blood pressure by means of the external measuring device with the atmospheric pressure as a reference. According to this embodiment, all the constituent parts such as the sensor element 21, the base 23 and the lead wires 33 are buried within the molding resin 39 that is shaped in the form of the distal end portion of a catheter type sensor, and the molding resin is capable of providing a enough strength required for a catheter in a minimum amount which is required to bury the constituent parts such as the sensor element 21. Accordingly, it is possible to considerably reduce the cross-sectional dimensions as compared with the conventional catheter type sensor.

Figs. 2(a), 2(b) and 2(c) show in combination another embodiment of the present invention arranged as a sensor type catheter which is most suitable for measuring central venous pressure (for

example, in a case where the catheter is inserted into a vein in the arm to measure blood pressure). In Fig. 2, the same reference numerals as those used in connection with the above-described embodiment denote similar constituent parts.

Since the blood flow velocity in the vein is relatively low, the blood readily coagulates to adhere to the outside of the catheter. Therefore, the catheter needs to have an outer shape which is as smooth as possible and has a uniform cross section. Further, since the rate of change with time of the venous pressure is relatively low (the measured pressure may almost be considered to be a static pressure), the measuring system is not required to respond quickly. Accordingly, the catheter in accordance with this embodiment is arranged so that the cross-sectional shape is circular throughout, including the peripheral portion of the sensor element 21, as illustrated. Although in this case the peripheral portion of the sensor element 21 is coated with a relatively thick layer of resin, there is no problem because high frequency response is not required as mentioned above. It should be noted that the portion around the sensor element 21 which is disposed at the distal end of the catheter is preferably formed from a particularly soft resin material so that the sensitivity of the sensor element 21 is improved and insertion of the catheter into blood vessels is facilitated.

Although in the above-described embodiments the sensor element 21 and the lead wires 33 are connected together through the wiring patterns 29 formed on the base 23, the lead wires 33 may also be electrically connected directly to the sensor element 21. In addition, it is possible to appropriately change the number of sensor elements 21 and bases 23 which can be mounted on a single catheter type sensor.

As has been described above, it is possible, according to the present invention, to provide a catheter type sensor having a smaller outer diameter than that of the conventional one. Since the catheter type sensor according to the present invention has a larger space for mounting sensor constituent parts than that of the conventional one provided that these sensors have the same outer diameter, it is possible to readily cope with the need to provide a sensor having a composite sensor means or a multiplicity of functions.

Instead of, or as well as, being located at the distal end of the catheter, the sensor assembly including the sensor element 21 and the base 23 may be located at the intermediate portion of it.

Claims

1. A catheter comprising:
a sensor assembly including a base (23) with

at least one sensor element (21) supported on it for detecting biological data, and a catheter body portion supporting the sensor assembly at its distal end or at an intermediate portion and including lead wires (33) for transmitting data between the sensor element (21) and an external measuring device, characterised in that the catheter is formed of a biocompatible resin material (39) in which the sensor assembly and the lead wires (33) are embedded.

2. A catheter according to Claim 1, wherein the synthetic resin material (39) is a urethane or silicone resin.
3. A catheter according to Claim 1 or 2, wherein the base (23) is formed from a sintered material which contains aluminum oxide as its principal component.
4. A catheter according to any of the preceding claims, wherein the sensor element (21) is connected to the external measuring device by a wiring pattern (29) formed on the base (23), the electrical connection between the wiring pattern (29) on the base (23) and the sensor element (21) being effected by wire bonding (31), and the electrical connection between the wiring pattern (29) and the lead wires (33) being effected by soldering.
5. A catheter according to Claim 4, wherein the bonding wires (31) are wedge bonded.
6. A catheter according to any of the preceding claims, wherein the sensor element is a pressure-sensitive element (21), and the portion of the catheter sensor which is to be inserted into a living body has a substantially uniform cross-sectional shape, including the peripheral portion surrounding the pressure-sensitive element (21).
7. A catheter according to Claim 6, wherein the portion of the catheter around the pressure-sensitive element (21) is formed from a soft resin material.
8. A catheter according to any of the preceding claims wherein the sensor element (21) is a semiconductor diaphragm type pressure sensor.
9. A catheter according to Claim 8, wherein the semiconductor diaphragm type pressure sensor (21) is connected to the surface of the base (21) using a gold-silicon alloy.

Revendications

1. Un cathéter comprenant :
un ensemble formant sonde comprenant une base (23) avec au moins un élément de sonde (21) supporté sur elle pour détecter des données biologiques, et une portion de corps de cathéter supportant l'ensemble formant sonde à son extrémité distale ou à une portion intermédiaire et comprenant des fils électriques (33) pour transmettre des données entre l'élément de sonde (21) et un dispositif de mesure externe, caractérisé en ce que le cathéter est formé d'un matériau d'une résine biocompatible (39) dans lequel l'ensemble formant sonde et les fils électriques (33) sont enfouis. 5
2. Un cathéter selon la revendication 1, où le matériau de résine synthétique (39) est une résine d'uréthane ou de silicone. 10
3. Un cathéter selon la revendication 1 ou 2, où la base (23) est formée à partir d'un matériau aggloméré qui contient de l'oxyde d'aluminium comme composant principal. 15
4. Un cathéter selon l'une quelconque des revendications précédentes, où l'élément de sonde (21) est relié au dispositif de mesure externe par un motif de fils (29) formés sur la base (23), la connexion électrique entre le motif de fils (29) sur la base (23) et l'élément de sonde (21) étant effectuée par liaison de fils (31), et la connexion électrique entre le motif de fils (29) et les fils électriques (33) étant effectuée par soudure. 20
5. Un cathéter selon la revendication 4, où les fils de liaison (31) sont liés par soudure. 25
6. Un cathéter selon l'une quelconque des revendications précédentes, où l'élément de sonde est un élément sensible à la pression (21), et la portion de sonde du cathéter qui doit être insérée dans un corps vivant a une forme en section transversale sensiblement uniforme, comprenant la portion périphérique entourant l'élément sensible à la pression (21). 30
7. Un cathéter selon la revendication 6, où la portion du cathéter autour de l'élément sensible à la pression (21) est formée à partir d'un matériau de résine doux. 35
8. Un cathéter selon l'une quelconque des revendications précédentes, où l'élément de sonde (21) est un détecteur de pression du type à diaphragme semiconducteur. 40

9. Un cathéter selon la revendication 8, où le détecteur de pression (21) du type à diaphragme semiconducteur est relié à la surface de la base (21) utilisant un alliage or-silicium. 45

Ansprüche

1. Katheter mit einer Sensoranordnung, die eine Grundplatte (23) mit mindestens einem auf der Grundplatte befestigten Sensorelement (21) zum Erfassen biologischer Daten enthält, und mit einem Katheterkörper, der die Sensoranordnung an seinem distalen Ende oder in seinem mittleren Bereich trägt und Anschlußdrähte (33) zur Datenübertragung zwischen dem Sensorelement (21) und einer externen Meßeinrichtung enthält,
dadurch gekennzeichnet, daß der Katheter aus einem biokompatiblen Harzwerkstoff (39) geformt ist, in den die Sensoranordnung und die Anschlußdrähte (33) eingebettet sind. 5
2. Katheter nach Anspruch 1,
dadurch gekennzeichnet, daß der synthetische Harzwerkstoff (39) ein Urethan- oder Silikonharz ist. 10
3. Katheter nach Anspruch 1 oder 2,
dadurch gekennzeichnet, daß die Grundplatte (23) aus Sinterwerkstoff geformt ist, der Aluminiumoxid als Hauptbestandteil enthält. 15
4. Katheter nach einem der vorstehenden Ansprüche,
dadurch gekennzeichnet, daß das Sensorelement (21) mit der externen Meßeinrichtung über auf der Grundplatte (23) geformte Leiterbahnen (29) verbunden ist, wobei die elektrische Verbindung zwischen den Leiterbahnen (29) und dem Sensorelement (21) durch Verbindungsdrähte (31) und zwischen den Leiterbahnen (29) und den Anschlußdrähten (33) durch Verlöten geschaffen ist. 20
5. Katheter nach Anspruch 4,
dadurch gekennzeichnet, daß die Verbindungsdrähte (31) festgeklemt bzw. verkeilt sind. 25
6. Katheter nach einem der vorstehenden Ansprüche,
dadurch gekennzeichnet, daß das Sensorelement (21) ein druckempfindliches Element ist und der in einen lebenden Körper einzuführende Abschnitt des Kathetersensors einschließlich des druckempfindlichen Element umgebenden Umfangsbereiches eine im wesentlichen gleichförmige Querschnittsform aufweist. 30

7. Katheter nach Anspruch 6,
dadurch gekennzeichnet, daß der das druckempfindliche Element umgebende Abschnitt des Katheters aus einem weichen Harzwerkstoff geformt ist. 5
8. Katheter nach einem der vorstehenden Ansprüche,
dadurch gekennzeichnet, daß das Sensorelement (21) ein Halbleiterdrucksensor des Membrantyps ist. 10
9. Katheter nach Anspruch 8,
dadurch gekennzeichnet, daß der Halbleiterdrucksensor des Membrantyps mit der Oberfläche der Grundplatte (23) unter Verwendung einer Gold-Silizium-Legierung verbunden ist. 15

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Fig. 1

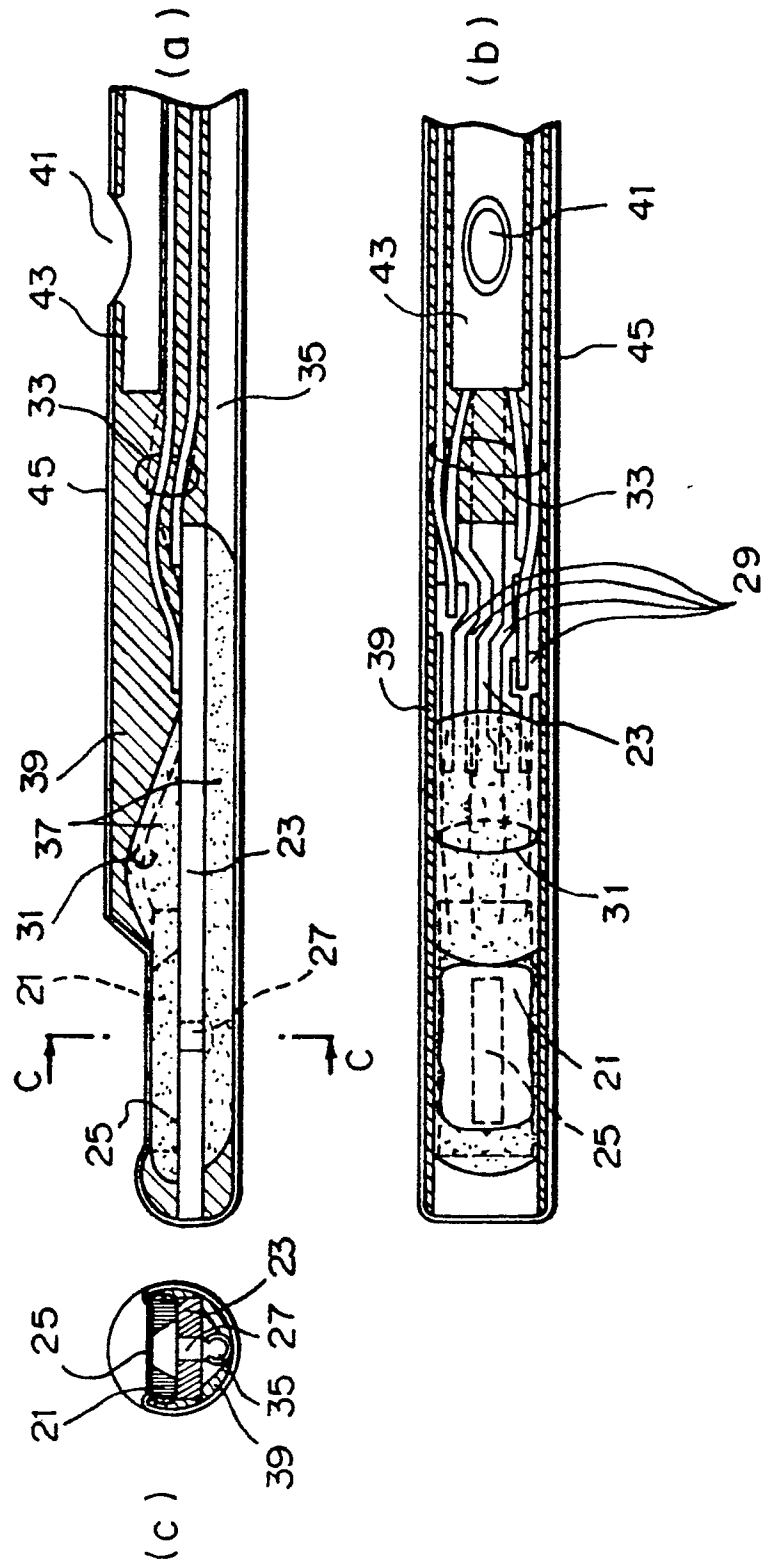


Fig. 2

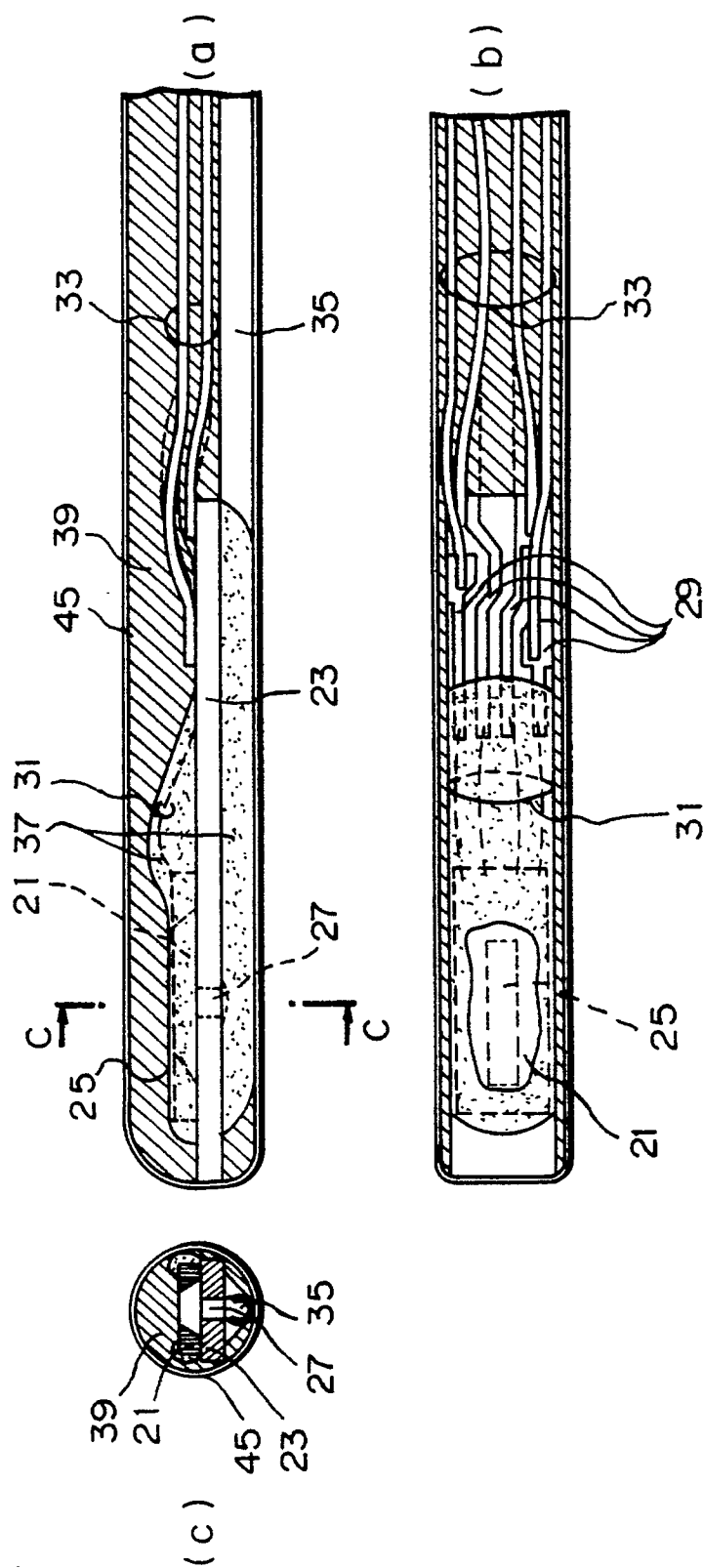


Fig. 3

